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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0547]

Clinical Development Programs for Sedation Products; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration's (FDA), Center for Drug Evaluation and Research (CDER) is announcing a scientific workshop to solicit information on a variety of issues related to the clinical development and use of sedation products in adult and pediatric age groups. FDA intends to take into account the information provided from this workshop as we develop FDA guidance on clinical development programs for sedation products. FDA issued a notice in the Federal Register of November 29, 2010, inviting an interested party, or parties, to facilitate an evaluation of the critical fundamentals of the science related to sedation products and to plan and conduct one or more public meetings to bring together experts in the field, including from academia, patient organizations, and industry, to discuss these issues. FDA has since determined that it will facilitate the evaluation itself, and as a first step, is announcing this workshop.

Date and Time: The public workshop will be held on May 3, 2012, from 8:30 a.m. to 5 p.m.

Location: The workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002.

Contact Person: Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3519, email: mary.gross@fda.hhs.gov; or Diana Walker, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4029, email: Diana.Walker@fda.hhs.gov.

Registration to Participate in Scientific Panels: If you wish to participate as part of a scientific panel, please email your request to CDER_Sedation_Workshop@FDA.HHS.gov by December 2, 2011. As part of your request, please describe your area of expertise and interest based on the questions identified below. If selected, a subset of panel representatives may be asked to provide formal presentations and /or participate in panel discussions

Registration to Attend the Workshop and Requests to Participate in Open Public Hearing: If you wish to attend or testify at the open public hearing, please email your registration to CDER_Sedation_Workshop@FDA.HHS.gov by April 2, 2012. Those without email access may register by contacting one of the persons listed in the Contact Person section of the document. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm221185.htm>.

An open public hearing will be held between 1:30 p.m. to 2:30 p.m. on May 3, 2012, during which speaker testimony will be accepted. We will try to accommodate all persons who wish to testify, however, the duration of each speaker's testimony during this open public hearing may be limited by time constraints.

Comments: Submit either electronic or written comments by July 3, 2012. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

If you need special accommodations due to a disability, contact Mary Gross or Diana Walker (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the Federal Register of November 29, 2010 (75 FR 73104), FDA indicated that it was seeking information on a variety of issues related to the clinical development and use of sedation products in adult and pediatric age groups. In the notice, FDA invited any interested party to take on the role of facilitating an evaluation of these issues and as a first step, plan or hold one or more public meetings to discuss these issues. FDA was going to take into account the information provided by these activities in the development of guidance on clinical development programs for sedation products. FDA has now determined that it will conduct the evaluation

itself, and is announcing this workshop to further understand the physiology of sedation and clinical trial design issues related to the development of sedation products.

FDA will explore the following topics during this public workshop:

1. For clinical trials of sedation drug products, which surgical and diagnostic procedures would provide the most relevant efficacy and safety data, while still allowing for a reasonable level of feasibility and efficiency?
2. What patient subgroups, other than pediatric, geriatric, and patients with hepatic or renal impairment, would require specific evaluation in clinical trials involving sedation drug products?
3. What is the most appropriate primary efficacy endpoint to assess in a clinical trial of a sedation drug product?
 - a. Which measurement scales have been adequately studied and validated for use in assessing the endpoint measure recommended previously
 - b. Is there a clinically meaningful effect size that should be considered as a minimal requirement for a determination of efficacy?
 - c. How do the responses to the previous questions differ, if at all, for the pediatric population, in particular, the youngest of these patients who have no or limited communication skills.
4. What secondary efficacy endpoints might be considered clinically meaningful (e.g., subjective and objective assessments of memory, recall, anxiety, agitation, or delirium) if appropriately studied?

5. How should responses to rapid changes in procedural stimulation be considered in the evaluation of efficacy, e.g., the time of initial incision or negotiating a colonoscope around the splenic or hepatic flexure.

6. How do the responses for each of the previous questions differ for evaluation of sedation products used in the operating room (OR), the intensive care unit (ICU), the emergency department (ED), and the gastro-intestinal (GI) suite?

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm221185.htm>.

II. Transcripts

Please be advised that approximately 30 days after the public workshop, a transcript will be available. It will be accessible at <http://www.regulations.gov> and may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: October 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.